WSA 2004 Proposed Project

Project Name:	Statistical data mining to provide alternative clinical trial designs for PREP Evaluation (N01467)
Purpose:	This project aims to explore data patterns and relationships and provide alternative clinical trial designs for future product development.

Reason for Doing this Work:
- ☐ Guidance
- ☒ Evaluation
- ☐ Product Design
- ☒ Short Term
- ☐ Long Term

Initiative and sub-initiative: (Check all areas that apply)

- ☐ Determinants of Exposure
  - ☐ Addiction
  - ☐ Ammonia
- ☒ Understanding Product Toxicity vs Product Design
  - ☒ Exposure
  - ☐ Carbon
  - ☐ Menthol
  - ☐ Low Tar
  - ☐ ETS
  - ☐ Specific Compounds
- ☒ Evaluation Framework Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☐ CVD
  - ☐ Molecular Biology
  - ☒ All Disease

- ☐ Evaluation Framework Non-Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☐ CVD
  - ☐ Molecular Biology
  - ☐ All Disease
- ☐ Broaden Flexibility after Clinical Studies
- ☐ Rapid Screening
- ☐ Knowledge Management
- ☐ Risk Assessment
- ☐ Communication
- ☐ Surveillance
- ☐ Smoking Conditions
- ☐ Improve Prep Subjectives
- ☐ Lit End Cigarette Reduced Exposure Design

Project Leader:	Q. Liang
Functional Area:	Clinical Evaluation

Prioritization: ☐ Critical ☐ Priority ☒ Secondary ☐ Low

Milestones:	Target Start Date:	Target Completion Date:
Project Plan	01/01/03	07/30/03
Investigate linear or nonlinear relationship between nicotine equivalents and other selected exposure biomarkers and develop predictive models for selected cigarette brands	01/01/03	To be integrated with a 2004 project
Investigate linear or nonlinear relationship between COHb and other selected exposure biomarkers and develop predictive models for selected cigarette brands	01/01/04	03/31/04
Explore some patterns and relationships important for alternative clinical trial designs.	04/01/04	09/30/04
Provide recommendations for design of exposure studies	10/01/04	12/31/04

Internal Resource Allocation (WSA, PMRL, PMI) (Man Hours)	External Resource Allocation (other PMUSA, external vendors) (Man Hours)
Qiwei Liang (120hrs.), Jingzhu Wang (120 hrs.), Julia Jin Yan (20 hrs.)	

TO BE FILLED OUT BY WSA MANAGEMENT
- ☐ Approved as Written
- ☐ Approved with Modifications
- ☐ Not Approved

Signature of Project Leader's Functional Director   (Date)

Last Revised: 12/10/03

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